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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/978,191	10/15/2001	Audrey Goddard	GNE.2630P1C4	4728

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EXAMINER	
O HARA, EILEEN B	
ART UNIT	PAPER NUMBER
1646	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/17/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/978,191	GODDARD ET AL.	
	Examiner	Art Unit	
	Eileen B. O'Hara	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 January 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *58-63 and 69-70* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *63* is/are allowed.

6)☒ Claim(s) *58-62,69 and 70* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims

1. Claims 58-63 and 69-70 are pending in the instant application.

Withdrawn Rejections

2. The rejections of claims under 35 USC § 101 and § 112 (enablement) is withdrawn in view of Applicants' arguments. A search conducted by the Examiner resulted in a number of other publications which demonstrate that in the majority of cases, change in expression of mRNA resulted in a concordant change in protein expression in a number of different biological systems and disorders/diseases. Additional supporting references are:

Lev et al., "Experimental encephalomyelitis induces changes in DJ-1: implications for oxidative stress in multiple sclerosis." Antioxidants & redox signaling, (2006 Nov-Dec) Vol. 8, No. 11-12, pp. 1987-95.

Yang et al., "Expression of netrin-1 in placenta from patients with pre-eclampsia and the relation to placental angiogenesis." Zhonghua fu chan ke za zhi, (2006 Sep) Vol. 41, No. 9, pp. 597-600.

Ma et al., "Reversion the multidrug resistance of human breast carcinoma cells by RNA interference targeting HIF-1 alpha gene." Zhonghua bing li xue za zhi Chinese journal of pathology, (2006 Jun) Vol. 35, No. 6, pp. 357-60.

Lv et al., "Effects of thalidomide on the expression of adhesion molecules in rat liver cirrhosis." Mediators of Inflammation, (2006) Vol. 2006. arn. 93253. Refs: 47

Lantuejoul et al., "Telomere shortening and telomerase reverse transcriptase expression in preinvasive bronchial lesions." Cancer Research: an official journal of the American Association for Cancer Research, (2005 Mar 1) Vol. 11, No. 5, pp. 2074-82.

Zhao et al., "Expression of interleukin-1-beta converting enzyme and its effect on cell apoptosis in cerebral ischemia-reperfusion injury." Chinese Journal of Clinical Rehabilitation, (7 Jul 2005) Vol. 9, No. 25, pp. 233-235.

Leite et al., "Co-expression and regulation of connexins 36 and 43 in cultured neonatal rat pancreatic islets." Canadian journal of physiology and pharmacology, (2005 Feb) Vol. 83, No. 2, pp. 142-51.

Pavelic et al., "The consequences of insulin-like growth factors/receptors dysfunction in lung cancer." American journal of respiratory cell and molecular biology, (2005 Jan) Vol. 32, No. 1, pp. 65-71. Electronic Publication: 2004-10-28.

Bu Cong-ya [Reprint Author]; Chen Yun-zhen, "Significance of abnormal expression of gp130] gene in rats after AMI and the effect of losartan on gp130." Zhonghua Xinxueguanbing Zazhi, (May 19 2004) Vol. 32, No. 5, pp. 446-450.

Li et al., "Effect of macrophage inflammatory protein-1alpha and its mRNA on airway inflammation of mouse asthma model." Zhonghua er ke za zhi. Chinese journal of pediatrics, (2004 Feb) Vol. 42, No. 2, pp. 90-3.

Gregor et al., "Mechanisms of myocardial remodeling: ramiprilat blocks the expressional upregulation of protein kinase C-epsilon in the surviving myocardium early after infarction." Journal of cardiovascular pharmacology, (2003 May) Vol. 41, No. 5, pp. 780-7.

de Lange et al. "Uncoupling protein-3 is a molecular determinant for the regulation of resting metabolic rate by thyroid hormone." Endocrinology, (2001 Aug) Vol. 142, No. 8, pp. 3414-20.

Lu et al. "Inhibition of PC cell-derived growth factor (PCDGF, epithelin/granulin precursor) expression by antisense PCDGF cDNA transfection inhibits tumorigenicity of the human breast carcinoma cell line MDA-MB-468." Proceedings of the National Academy of Sciences of the United States of America, (2000 Apr 11) Vol. 97, No. 8, pp. 3993-8.

Schwartz et al., "Developmental expression of cytochrome P450 side-chain cleavage and cytochrome P450 17 alpha-hydroxylase messenger ribonucleic acid and protein in the neonatal hamster ovary." Biology of reproduction, (2000 Dec) Vol. 63, No. 6, pp. 1586-93.

Darmanto et al., "Derangement of Purkinje cells in the rat cerebellum following prenatal exposure to X-irradiation: decreased Reelin level is a possible cause." Journal of neuropathology and experimental neurology, (2000 Mar) Vol. 59, No. 3, pp. 251-62.

Chen et al., « p53 mRNA expression in non-Hodgkin's lymphomas." Journal of Shanghai Medical University, (Nov., 1999) Vol. 26, No. 6, pp. 428-430. print.

Xie et al., "Up-regulation of liver glucose-6-phosphatase in rats fed with a P(i)-deficient diet." The Biochemical journal, (1999 Oct 15) Vol. 343 Pt 2, pp. 393-6.

Liu et al., "Regulation of gp330/megalin expression by vitamins A and D." European journal of clinical investigation, (1998 Feb) Vol. 28, No. 2, pp. 100-7.

Su et al., "Expression of cytokeratin messenger RNA versus protein in the normal mammary gland and in breast cancer." Human pathology, (1996 August) Vol. 27, No. 8, pp. 800-6.

Santalucia et al., "Developmental regulation of GLUT-1 (erythroid/Hep G2) and GLUT-4 (muscle/fat) glucose transporter expression in rat heart, skeletal muscle, and brown adipose tissue." Endocrinology, (1992 Feb) Vol. 130, No. 2, pp. 837-46.

Maintained Rejections

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 58-62 and 69-70 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The basis of this rejection is set forth in the Office Action mailed June 2, 2004, at pages 5-9, March 16, 2005 at pages 3-10, Sept. 20, 2005, Feb. 8, 2006 and September 27, 2006.

Applicant's arguments (pp. 18-19, remarks submitted January 26, 2006) have been fully considered but are not found to be persuasive for the following reasons.

Applicants submit that that the Examiner's arguments that "80% identity to a described sequence is not a true structure" is not consistent with Example 14 of the Synopsis of

Application of Written Description Guidelines issued by the U.S. Patent Office, which makes clear that a defined degree of homology to a reference sequence, when combined with known procedures for making variant proteins and an assay for detecting the functional activity of the variants, is sufficient to provide adequate written description for the variant polypeptides, and that there is simply no requirement in the Guidelines for a disclosure of precisely which amino acids are important for activity. Applicants further assert that the property of being overexpressed in tumors is a functional limitation, and cite *In re Swinehart*. Applicants submit that the law is clear that "[a] functional limitation is an attempt to define something by what it does, rather than by what it is (e.g., as evidenced by its specific structure or specific ingredients)."A functional limitation is often used in association with an element, ingredient, or step of a process to define a particular capability or purpose that is served by the recited element, ingredient or step." Accordingly, overexpression of the claimed polypeptides in lung tumor cells is a functional limitation which indicates the functional purpose (i.e., use in the diagnosis of cancer) of the claimed polypeptides.

Applicants' arguments have been fully considered but are not deemed persuasive. While one of ordinary skill in the art would know how to make a protein 80% identical to the protein of SEQ ID NO: 506, because it is overexpressed in lung tumors, it must be a naturally occurring protein, and Applicants have only described a single naturally occurring polypeptide. Also, while it would be possible to isolate proteins from lung tumors and to determine homology to the protein of SEQ ID NO: 506, Applicants have not provided any evidence that such proteins exist. The instant disclosure of a single polypeptide, that of SEQ ID NO: 506, does not adequately support the scope of the claimed genus, which encompasses a substantial variety of subgenera.

A genus claim may be supported by a representative number of species as set forth in *Regents of the University of California v Eli Lilly & Co,* 119F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997), which states:

"To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention". Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1980) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed.") Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d 1565, 1572, 41 USPQ2d at 1966.

An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. Fiers v. Revel, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id at 1170, 25 USPQ2d at 1606."

It is believed that all pertinent arguments have been answered.

Conclusion

4.1 Claim 63 is allowed.

4.2 Claims 58-62 and 69-70 are rejected.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (571) 272-0878. The examiner can normally be reached on Monday through Friday from 10:00 AM to 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nichol can be reached at (571) 272-0835.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://portal.uspto.gov/external/portal/pair. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Eileen B. O'Hara, Ph.D.

Patent Examiner

Eileen B. O'Hara

EILEEN B. O'HARA
PRIMARY EXAMINER